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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,214	03/20/2001	Kenneth Tucker	71515-199	1989

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DICKINSON WRIGHT PLLC
1901 L. STREET NW
SUITE 800
WASHINGTON, DC 20036

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,214

Applicant(s)

TUCKER ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-8,13-16,27,29,35,40,52-54 and 57-64 is/are pending in the application.
- 4a) Of the above claim(s) 13-16,27,29,35 and 40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8,52-54,57 and 59-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed December 13, 2005 has been received and entered. Claims 3-4, 9-12, 17-26, 28, 30-34, 36-39, 41-51, and 55-56 have been canceled. Accordingly, claims 1-2, 5-8, 13-16, 27, 29, 35, 40, 52-54, 57-64 are pending in the instant application, of which claims 13-16, 27, 29, 35, and 40 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

1. The rejection of claim 59 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is maintained.

Applicants assert that claims 58-63 have been amended to recite an "isolated OMP106 polypeptide" and therefore overcomes the rejection.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants have indeed amended claims 58 and 60-63 to recite an isolated OMP106 polypeptide and this amendment is sufficient to overcome the rejection as applied to these claims. However, claim 59 has not been amended to recite this term, and only includes structural limitations of the protein found naturally, e.g., SEQ ID NO: 1. As such this naturally occurring polypeptide is deemed to be non-statutory subject matter.

Claim 59 is directed to a polypeptide which is the same as those found naturally and therefore does not constitute as patentable subject matter.

It is noted that Applicants claims recite "chimeric" however, given that the identity

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or structure of the molecule which makes the polypeptide "chimeric" is not set forth, it is not sufficient to distinguish over the naturally occurring polypeptide, which is the only structural limitation found in the claim.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated OMP106 polypeptide..."

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 112

2. The rejection of claims 3-4 under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure without complete evidence that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of biological materials is withdrawn in view of the cancellation of said claims.

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3. The rejection of claims 1-2, 5-8, 52-54, 57, and 59-64 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the scope of the claims has been amended to a narrowly drawn limited number of biosequences recognized by an antibody that specifically binds a polypeptide having defined amino acid sequences. Applicants assert that all claims are limited to defined amino acid sequences in addition to immunogenic properties, therefore, these polypeptides must have a conserved structure and is clearly immunogenic to *Moraxella catarrhalis*.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that the scope of the claims has been amended to a narrowly drawn limited number of biosequences recognized by an antibody that specifically binds a polypeptide having defined amino acid sequences. However, Applicants are respectfully directed back to the claims, which recites the phrase “comprising the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 9.” SEQ ID NO: 1 is only a fragment of a full length protein, i.e., 43 amino acids in length. It is precisely this fragment, which does not meet the written description guidelines when combined with the phrase “comprising” which encompasses numerous structural divergence upstream and downstream from the specifically identified fragment. Turning towards the Written Description Guidelines, Applicants will appreciate that a genus can be satisfactorily described by identifying a function exhibited by the protein, (e.g., particular enzymatic activity).

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However, merely asserting that the claimed protein cross reacts with an antibody elicited against a fragment of the protein is not sufficient to identify members of the genus. It is merely an attempt to further identify several other undescribed proteins of unknown function. Furthermore, every protein will be immunogenic under the right conditions, consequently, Applicants limitation of binding an antibody, does not adequately describe the members of the genus.

Claims 1-2, 5-8, 52-54, 57, and 59-64 recite an isolated or purified OMP106 polypeptide, to between 70% and 99% pure by weight, which is an outer membrane polypeptide of *Moraxella catarrhalis*, and which has a molecule weight of about 180 kD to about 230 kD as determined in SDS polyacrylamide gel electrophoresis using rabbit skeletal muscle myosin and *E. coli* β -galactosidase as the 200kD and 116.25 molecular weight standards, respectively and which comprises the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 9.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "SEQ ID NO: 1" alone is insufficient to describe the genus. Specifically, SEQ ID NO: 1 lacks a start codon and a stop codon for translation. Without providing description of both a start and a stop codon, Applicants have only provided support for the specifically identified fragment, i.e., "consisting of SEQ ID NO: 1." One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus,

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applicant was not in possession of the claimed genus. Additional nucleotides upstream or downstream of this region will have a profound impact on the activity of the encoded protein. While Applicants have disclosed the full length sequence of the protein, only the exact sequence of this full length protein is sufficiently described, not any protein “comprising a fragment of this protein, i.e., SEQ ID NO: 1.”

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the

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claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.”

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claim 64 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of “high stringency conditions” is withdrawn in view of Applicants arguments.

The following new grounds of rejection are applied:

Specification

5. The amendment filed December 13, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to the continuing data statement includes the phrase “”incorporated by reference to the

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extent allowed by law.” Applicants may only add this phrase at the time of filing, any attempt to later introduce incorporation, is deemed new mater.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim 58 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
February 22, 2006